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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,468	03/15/2001	Michael Wholey	180431-00015	5503

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PIETRAGALLO, BOSICK & GORDON LLP  
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PITTSBURGH, PA 15219-6404

EXAMINER
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DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/809,468

Applicant(s)

WHOLEY ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 12-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 8-11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,406,786 to Hein in view of US 4,399,042 to Stannard et al.

In the specification and figures, Hein discloses the apparatus substantially as claimed by applicant. In particular, Hein discloses a filter device with an elongated chamber (1, 3, 6), a paddle assembly 5 disposed within the chamber, a porous floor 8 disposed within and extending across the chamber, and means for coupling (2, 7) the filter device to an artery and a vein (see columns 3-4, FIG 2).

With regard to applicant's "means for coupling" of claim 1, the language appears to be an attempt to invoke 35 USC 112, 6<sup>th</sup> paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for" or "step for;"
- (B) the "means for" or "step for" must be modified by functional language;  
and
- (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for applicant's definition.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." (MPEP § 2181). Applicant's specification discloses that tubes 21 and 33 connect to the filter and, in turn, are connectable to patient blood vessels. Hein discloses that the ends of his filter device comprise tubes 2, 7, which perform the same function as the claimed "means for coupling," since both structures channel fluid from a source through the filter and back out. Therefore, examiner considers Hein's tubes 2, 7, to be the functional equivalent of applicant's "means for coupling," meeting the limitations of the claim.

Hein fails to disclose porous paddles. With regard to claims 2 and 3, Stannard discloses a filter apparatus with a porous filter bed 26 and paddles or blades 44 that agitate the fluid in the filter chamber and scrape the particulate material from the filter bed (see column 4, FIGS 4-5). The blades are mounted on and rotate about a vertical shaft 42 that supports the blades (see column 5, lines 40-45), and may comprise a porous structure that allows water or fluid to pass through them while retaining the solids in the filtered fluid (see column 6, lines 26-38). The paddles have a front and a back surface (see FIG 6) and horizontal holes 160 drilled in the blade 152 (see FIG 10) in order to assist in removal of filter cakes from the apparatus (see column 6, lines 15-20). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the agitating means or paddles disclosed by

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Hein with porous surfaces and a rotator shaft as disclosed by Stannard in order assist in removal of filter cakes from the apparatus, as taught by Stannard (see column 6, lines 15-20).

With regard to claim 2, Stannard illustrates a vertical axis 42 and paddles 94 extending therefrom (see FIG 6). With regard to applicant's recitation of "micro pores," examiner has interpreted the limitation (absent any specific allusion to size in the specification) to mean small pores that allow only fluid to pass through, while retaining clots. ("Micro" is broadly interpreted by the examiner to merely mean "very small." See Merriam Webster's Collegiate Dictionary, 10<sup>th</sup> Ed, 2001.) Stannard specifically discloses that the porosity of the blades are selected to allow fluid to pass, but not particulate matter. Since the Stannard device functions in the same manner as claimed by applicant, and applicant fails to disclose the size of the claimed "micro pores," the combined Hein and Stannard disclosures meet the limitation of the claim.

With regard to claim 3, Stannard illustrates a vertical shaft 186 that extends from porous floor 172 along the axis of the filter chamber (see FIG 11).

With regard to claim 4, Hein discloses a cylindrical chamber with a proximal end 1 and a distal end 6, wherein the filter bed 4 is disposed at distal end 6 (see FIG 1).

With regard to claim 5, Stannard specifically discloses that the filter bed may filter particulate matter from a fluid flowing past the filter. Since the filter disclosed by Hein and Stannard is capable of performing the filtering function claimed by applicant, it meets the limitations of the claim.

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3. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,406,786 to Hein in view of US 4,399,042 to Stannard et al, as applied above, further in view of US 6,059,745 to Gelbfish.

In the specification and figures, Hein and Stannard disclose the apparatus as claimed by applicant with the exception of one-way valves at the inlet and outlet of the filter device. Gelbfish discloses a thrombectomy apparatus with an anterior inlet end (generally at 18) and a distal outlet end (generally at 14) and a filter chamber 21 with a porous filter 20 disposed in the chamber to trap blood clots. The device comprises one way-valves 30 and 32 in the anterior and distal ends of the device in order to prevent backflow of trapped clots to the patient (see column 6, lines 35-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the one-way valves disclosed by Gelbfish to the filtration apparatus disclosed by Hein and Stannard in order to prevent backflow of debris to the patient, as taught by Gelbfish.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,406,786 to Hein in view of US 4,399,042 to Stannard et al, in view of US 6,059,745 to Gelbfish, as applied above, further in view of US 6,416,665 to McGrath.

In the specification and figures, Hein, Stannard, and Gelbfish disclose the device as claimed with the exception of a motor or engine that drives the shaft. Stannard specifically discloses that the device may comprise drive motor 218, but does not disclose that it comprises a separate shaft that is coupled to blade shaft 42. McGrath discloses a filtration apparatus wherein a filtration membrane 4 is mounted on axis 5

and rotated about chamber 3. The axis 5 is coupled by a pulley 8 to a shaft (unlabeled) that is driven by motor 9 (see FIG 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the motor and drive system disclosed by McGrath to the filtration system disclosed by Hein, Stannard, and Gelbfish in order to provide rotational motion to the axis and filtration membrane, as taught by McGrath.

#### ***Allowable Subject Matter***

5. Claims 8-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the invention claimed by applicant. In particular, the prior art fails to disclose a filter as set forth in the independent claim with a cylindrical housing, a porous floor, porous paddles, valves, drive motor and shaft as claimed, and coupling structure as claimed, along with the other steps and limitations of the claims.

#### ***Response to Arguments***

7. Applicant's amendment and arguments filed 10 November 2006 have been entered and considered.

8. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments with respect to claims 2-7 have been fully considered but they are not persuasive.

10. Applicant argues that the Hein and Stannard devices are not analogous to the art of thrombectomy devices. While pressure filter devices and sludge filters are not medically oriented, both devices deal with the process of filtering fluid, which is essentially the function of a thrombectomy device. Both the instant invention and the prior art separate solids from liquids by passing a stream of fluid through a semipermeable membrane, solving the common problem of removing debris from a solution. Since the instant invention and the prior art are directed to solving the same problem, the application of the cited art to the instantly claimed invention is proper.

11. Applicant further argues that the prior art does not comprise paddles with a front and rear exterior surface defining a thickness with pores extending through the paddle. However, Stannard clearly illustrates a paddle or blade 152 that comprises a thickness (see FIG 6), with pores 160 that extend through the thickness (see FIG 10), meeting the limitations of the claims.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



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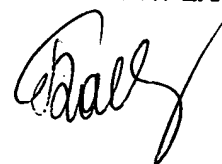
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

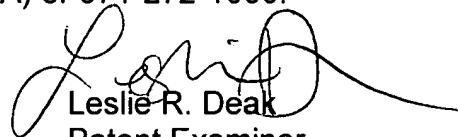
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**TATYANA ZALUKAEVA**  
**SUPERVISORY PRIMARY EXAMINER**



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Leslie R. Deak', with a long horizontal flourish extending to the right.

Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
11 January 2007